APPENDIX 3.8.5.

FACTORS TO CONSIDER IN CONDUCTING THE BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT RECOMMENDED IN CHAPTER 2.3.13.

Article 3.8.5.1.

Introduction

The first step in determining the bovine spongiform encephalopathy (BSE) risk status of the cattle population of a country, *zone* or *compartment* is to conduct a risk assessment (reviewed annually), based on Section 1.3 of this *Terrestrial Code*, identifying all potential factors for BSE occurrence, their historical perspective and the risk management measures which have been adopted to prevent cattle from becoming infected:

1) Release assessment

Release assessment consists of assessing, through consideration of the following, the likelihood that the BSE agent has either been introduced into the country, *zone* or *compartment* via *commodities* potentially contaminated with it, or is already present:

a) the presence or absence of the BSE agent in the indigenous ruminant population of the country, *zone* or *compartment* and, if present, evidence regarding its prevalence;

b) production of *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

c) imported *meat-and-bone meal* or *greaves*;

d) imported cattle, sheep and goats;

e) imported animal feed and feed ingredients;

f) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13. and may have been fed to cattle;

g) imported products of ruminant origin intended for *in vivo* use in cattle.

The results of any epidemiological investigation into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

2) Exposure assessment

If the release assessment identifies a *risk* factor, an exposure assessment should be conducted, through a consideration of the following, to assess the likelihood of exposure of cattle to the BSE agent:

a) the epidemiological situation concerning BSE in the country or *zone*;

b) the potential for recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

c) the origin and use of bovine, caprine or ovine carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

d) the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;

e) the level of surveillance for BSE conducted on the cattle population to that time and the results of that surveillance.

The following guidelines are intended to assist *Veterinary Services* in conducting such a risk assessment.

Article 3.8.5.1.(bis)

The presence or absence of the BSE agent in the indigenous ruminant population

Assumptions:

- While cattle pose the only demonstrated risk, and must be regarded as the best "indicator species" for the presence of BSE in a country, BSE has recently been demonstrated in a goat and there is potential for it to also be present in sheep.

- If a surveillance programme for BSE in cattle, as described in Appendix 3.8.4. is in place for an appropriate length of time and has failed to detect cases, it can be assumed that the disease is unlikely to be present in small ruminants.

- The BSE status of a country may change as more data become available; this may result from a change in status of any risk factor such as, for example, the detection of clinical disease, following active surveillance, or assessment of geographical BSE risk;

Question to be answered: Is a BSE surveillance programme as described in Appendix 3.8.4. in place? If so, for what period of time? Has BSE been identified in the country?

Rationale: Surveillance programmes generate a picture of the epidemiological situation of BSE. The greater the surveillance effort, the greater the power of the information. Adequately targeted surveillance for BSE, such as described in Appendix 3.8.4., provides more powerful information than generic animal disease surveillance. Failure of an appropriate surveillance programme as described in Appendix 3.8.4., conducted for a period of 7 years (Article 2.3.13.3.) to detect a case of BSE indicates that either the agent was not released into the country, *zone* or *compartment*, or cattle were not exposed to the agent, or the production system was sufficiently stable to prevent the agents amplifying and recycling.

Evidence required: Documentation on awareness and surveillance programmes for BSE, their legal basis, scale, duration, and data generated.

Article 3.8.5.1. (tris)

The potential for the release of the BSE agent through meat-and-bone meal or greaves of local origin, or livestock feedstuffs potentially contaminated with them

This point is irrelevant if the exposure assessment outlined below in Article 3.8.5.5. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants.

Assumption: That *meat-and-bone meal* or *greaves* of bovine, caprine or ovine origin plays the only significant role in BSE transmission.

Question to be answered: Has *meat-and-bone meal* or *greaves* of local origin been used in livestock feedstuffs in the past? If so, where from which species and in what quantities? If so, what level of risk does this present?

Rationale: Knowledge of the origin of *meat-and-bone meal* or *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves*, is necessary to assess the risk of release of BSE agent.

Evidence required:

- Documentation to support claims that *meat-and-bone meal* or *greaves* of local origin have not been used in livestock feedstuffs, OR
- Where *meat-and-bone meal* or *greaves* of local origin have been used in livestock feedstuffs, documentation on annual volume.
- Documentation describing the composition (tissues used and species and class of stock) of the *meat-and-bone meal* or *greaves* of local origin.
- Documentation supporting why the rendering processes used to produce *meat-and-bone meal* or *greaves* of local origin would have inactivated, or significantly reduced the titre of the BSE agent, should it be present.
- Documentation describing the fate of locally-produced *meat-and-bone meal* and *greaves.*

Article 3.8.5.2.

The potential for the release of the BSE agent through importation of meat-and-bone meal or greaves or livestock feedstuffs potentially contaminated with them

This point is irrelevant if the exposure assessment outlined below in Article 3.8.5.5. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants.

Assumption: That *meat-and-bone meal* or *greaves* of bovine, caprine or ovine origin plays the only significant role in BSE transmission.

Question to be answered: Has *meat-and-bone meal* or *greaves*, or feedstuffs containing either, been imported in the past? If so, when and where from and in what quantities? If so, what level of risk does the importation present?

Rationale: Knowledge of the origin of *meat-and-bone meal* or *greaves*, or feedstuffs containing either, is necessary to assess the risk of release of BSE agent.

Evidence required:

- Documentation to support claims that *meat-and-bone meal* or *greaves*, or feedstuffs containing either, have not been imported, OR

- Where *meat-and-bone meal* or *greaves,* or feedstuffs containing them, have been imported, documentation of country of origin and, if different, the country of export.

- Documentation on dates of imports and annual volume, by country of origin, of *meat-and-bone meal* or *greaves,* or feedstuffs containing them, imported in the past.

- Documentation describing the composition (tissues used and species and class of stock) of the imported *meat-and-bone meal* or *greaves,* or feedstuffs containing them.
- Documentation, from the country of production, supporting why the rendering processes used to produce *meat-and-bone meal* or *greaves,* or feedstuffs containing them, would have inactivated, or significantly reduced the titre of the BSE agent, should it be present.
- Documentation describing the fate of imported *meat-and-bone meal*, *greaves* and feedstuffs.

Article 3.8.5.3.

The potential for the release of the BSE agent through the importation of bovine, caprine and ovine animals

Assumptions:

- Countries which have imported cattle from countries infected with BSE are more likely to experience BSE.
- Countries which have imported caprine and ovine animals from countries infected with BSE may be more likely to experience BSE, although this risk is largely hypothetical.
- Animals imported for breeding may pose a greater risk than animals imported for slaughter because they are typically kept to a greater age than animals imported for slaughter.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 1.3.2.3).

Question to be answered: Have bovine, caprine or ovine animals been imported at any time since 1980? If so, what level of risk does the importation present?

Rationale: The release risks are dependent on:

- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical disease, or following active surveillance, or assessment of geographical BSE risk;
- the *exporting country*'s policies with respect to the feeding to livestock of rations containing protein of animal origin;
- how imported ruminants were disposed of at the end of their productive life and whether their tissues could have been rendered into *meat and bone meal* or *greaves*;
- species of ruminant animals imported;

- factors such as production type (e.g. dairy versus meat breeds), geographic location and the potential influence of culturally unique husbandry practices which may give rise to differences in exposure in the country of origin because feeding practices result in greater exposure of one category;

- age at slaughter or death;

- fate (rendered, incinerated, buried) and, if tested for BSE, the results.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of birth, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing numbers, origins and species imported.
- Documentation describing the fate of imported animals, including their age at slaughter or death and, if tested for BSE, the results.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 3.8.5.4.

The potential for the release of the BSE agent through the importation of products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13.

Assumptions:

- Current scientific evidence strongly indicates that semen, embryos, muscle meat, gelatine, blood and blood products, protein-free tallow, hides and skins, and milk play no role in the transmission of BSE.
- Countries which have imported products of bovine, caprine or ovine origin containing or contaminated with tissues listed in Article 2.3.13.13. from countries with BSE are more likely to experience BSE.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 1.3.2.3).

Question to be answered: What products of bovine, caprine and ovine origin potentially containing or contaminated with tissues listed in Article 2.3.13.13. have been imported in the past? What level of risk does the importation present?

Rationale: The release risks are dependent on:

- the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 2.3.13.13);
- dates and annual volumes of imports;
- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical disease, or following active surveillance, or assessment of geographical BSE risk;

- temperature, time and pressure parameters of processes used in the manufacture of the products;
- the *exporting country*'s policies with respect to the feeding to livestock of rations containing protein of animal origin;
- whether products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13. may have been diverted from intended use and been rendered into *meat-and-bone meal* or *greaves*.

Evidence required:

- Documentation on the country of origin of imports of products potentially containing or contaminated with tissues listed in Article 2.3.13.13. This should identify the country of birth of bovine, caprine and ovine animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the end use of imported animal products, and the disposal of waste.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 3.8.5.5.

The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of bovine, caprine or ovine origin

Assumptions:

- That the consumption by bovines of *meat-and-bone meal* or *greaves* of bovine, caprine or ovine origin plays the only significant role in BSE transmission.
- That commercially-available products of animal origin used in animal feeds may contain *meat-and-bone meal* or *greaves* of bovine, caprine and ovine origin.
- Milk and blood are not considered to play a role in the transmission of BSE.

Question to be answered: Has *meat-and-bone meal* or *greaves* of bovine, caprine or ovine origin ever been fed to ruminants? If so, what level of risk does the practice present?

Rationale: If cattle have never been fed products potentially containing *meat-and-bone meal* or *greaves* of bovine, caprine or ovine origin, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

Evidence required: Documentation on feeding practices and feed bans, and measures to prevent cross-contamination of animal feed.

Article 3.8.5.6.

The potential for the release of the BSE agent through the importation of products of ruminant origin intended for *in vivo* use in cattle

Assumptions:

- TSEs have been demonstrated to be transmissible between animals iatrogenically, through the use of tissues containing potentially high levels of infectivity in the manufacture of vaccines in particular. Although such records relate specifically to the use in small ruminants of vaccines derived from brain or mammary tissue, the use of bovine brain for such purposes must also logically present a risk.

- International guidelines for the production of veterinary biological medicinal products recognise these risks, and aim to mitigate them by safe sourcing (as in Article 2.3.13.13) coupled, where necessary, by safe production methods.

Questions to be answered:

- Have veterinary biological medicinal products ever been imported from countries at risk of BSE?
- Would such products be manufactured by companies that guarantee compliance with international guidelines on the manufacture of veterinary medicinal products?
- Are individuals permitted to produce veterinary biological medicinal products that are not subject to national regulation, such as for use only within the herd or flock of origin, and is there potential for source materials to be derived from other countries?

Rationale:

- Scrapie has been demonstrated to be transmissible through the administration of vaccines against louping ill and against *Mycoplasma agalactiae*, which have been produced from ovine brain tissue and mammary tissue respectively. Parenteral inoculation of products containing such tissues, or organs such as the pituitary gland, is an effective means of transmitting infection. Similar risks could arise with regard to bovine derived vaccines which involved brain, spinal cord or pituitary gland.

Evidence required:

- Documentary evidence of national controls over the manufacture, importation and use of veterinary medicines.
- Specific documentation on products that contain, or have used bovine, ovine or caprine brain tissue as a substrate in manufacture.

Article 3.8.5.7.

The fate of tissues listed in Article 2.3.13.13, the parameters of the rendering processes and the methods of animal feed production

Assumptions:

- BSE has a long incubation period and insidious onset of signs, so cases may escape detection.
- Except for cases in the late *incubation period*, pre-clinical BSE cannot be detected by any method and may enter rendering, in particular if specified risk materials are not removed.
- BSE may manifest in chronic disease or recumbency, and may be presented as fallen stock.
- Tissues listed in Article 2.3.13.13 (including tissues most likely to contain high titres of BSE infectivity) may be present in materials condemned as unfit for human consumption and may be rendered.

- BSE agent survival in rendering is affected by the method of processing. Rendering processes are described in Appendix 3.6.3.

Question to be answered: How has material containing tissues listed in Article 2.3.13.13 been processed in the past?

Rationale: If potentially infected animals or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity.

Where *meat-and-bone meal* is utilized in the production of any animal feeds, the risk of cross-contamination exists.

Evidence required:

- Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.

- Documentation describing the definition and disposal of specified risk material, if any.

- Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.

- Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of *meat-and-bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.

- Documentation describing monitoring and enforcement of the above.

Article 3.8.5.8.

The overall risk of BSE in the cattle population of a country, *zone* or *compartment* is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the risk assessment to conclude that the cattle population of a country, *zone* or *compartment* poses a negligible BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified.